REMARKS

Upon entry of the above amendments, this application will contain claims 1-16 and 27-56 pending and under consideration. The application was originally filed with claims 1-29. Claims 17-26 were canceled and new claims 30-53 were added in a Response to Restriction Requirement. In the present Response, claims 1, 10, 15, 43, 44, 51, and 53 have been amended, and new claims 54, 55, and 56 have been added.

In view of the discussion below, it is believed that the claimed invention is patentably distinct over the cited references. Therefore, withdrawal of all remaining rejections and objections and allowance of this application is requested.

Objections to the Specification

Objections were raised to the specification, particularly on page 6, line 16, for including the word "or" twice. This paragraph has been amended. It is believed that the amendments do not add any new matter.

Objections were for "numerous page breaks within the disclosure beginning with page 1 following through to page 5." (Office Action, para. 2, pages 2 and 3.) The undersigned has reviewed the written specification and believes that it fully comports to the requirements specified in patent statutes, the Code of Federal Regulations (see especially 37 CFR §§1.52 and 1.77 and the MPEP §§601.01 and 608.01). It is believed that there are no prohibitions of page breaks separating the major section divisions in an application.

Objections were raised to the title of the invention. It was suggested in the Office Action that "new or novel" should not be used in the title of the application. The Applicants do not believe that this is a specific requirement recited in the MPEP or any of the patent laws or under current patent law practice. (MPEP §§606 and 606.01.) However, in order to advance the prosecution of this application, the Applicants have amended the title by deleting the word "novel". It is believed that this amendment does not add any new matter.

Amendments to the Claims

Objections were raised to claim 10 for a minor typographical error. Claim 10 has been amended to replace the word "ganliosides" with the word --gangliosides--. Similarly, claims 43

and 44 have both been amended for minor typographical errors to replace the word "chemcial" with the word --chemical--.

Claim 15 was rejected for reciting the phrase "such as". Claim 15 has been amended to delete this phrase.

Claims 51 and 53 have been amended to delete the duplicate phrase "said method comprising".

It is believed that these amendments do not add any new matter.

Rejections Under 35 USC §112

Claims 1, 4-16, and 27-49 were rejected under 35 USC §112, first paragraph. This rejection is respectfully traversed. It was stated in the Office Action that "the claims are not limited to any specific antigen and thus include HIV antigens" and that "the specification lacks guidance and teaching to show that, for example, the composition comprising a phytol derivative as an adjuvant and a vaccine antigen, e.g., HIV antigen, was generated or extracted and used to prevent infection." (Office Action, page 4, para. 4.) The Applicants respectfully traverse this rejection. It is maintained that for a specification to be enabling, only a representative number of species within a genus are required to be described. (See Guidelines for Examination to Patent Applications Under the 35 USC §112, 1, 'Written Description' Requirement, *Official Gazette Notices - 30 January 2001.*) The scope of enablement must bear a "reasonable correlation" to the scope of the claims. In re Fisher, 166 USPQ 18,24 (CCPA, 1970) Furthermore, the presence of allegedly inoperative embodiments, i.e., HIV antigens, does not render a claim non enabled. (Atlas Powder Co. v. E.I. duPont de Nemours & Co., 224 USPQ 409, 414 (Fed Cir 1984) and MPEP §2164.08(b) (2004).) Therefore, the Applicant believes that the invention claimed in claims 1, 4-16, and 27-49 is adequately supported and enabled by the written description.

However, to advance the prosecution of the application, claim 1 has been amended to recite that the composition comprises a vaccine preparation effective for the treatment of a mammal. Support for the amendment can be found in the application on page 6, lines 14-16. Therefore, it is believed that this amendment does not add new matter. Withdrawal of the rejections of claims 1, 4-16, and 27-49 is requested.

Claim Rejections Under 35 USC §102

Claims 1, 6-11, and 27-49 were rejected under 35 USC §102(b) over Stewart, Jr. et al. (US 6,406,885, "Stewart"), in view of Takayuki Suga et al. (Glycinoprenols: Novel polyprenols possessing a phytyl residue from the leaves of soybean, *J. Org. Chem.*, 1989, 54, 3390-3393, "Suga").

The Applicant traverses this rejection. Rejections under §102 must rely on a single reference that discloses every aspect of the claimed invention either explicitly or inherently. Therefore, it is assumed that the reference Suga is cited merely to show that soybeans comprise polyprenes. What Suga actually discloses is that six polyprenols, structures 1-6, were isolated from the leaves of soybeans. It is believed that Stewart does not anticipate or make obvious the claimed invention which includes a composition comprising a vaccine in unit dosage form. All that Stewart provides is that animals can be fed engineered plants (soybeans) that express intimin antigen or the intimin fusion protein from *E. coli*. Neither of these references either considered singly or together disclose or suggest a composition as instantly claimed with a vaccine in a unit dosage form. Merely feeding an animal engineered soybeans does not constitute a unit dosage form of a vaccine preparation. Therefore, withdrawal of the rejections of claims 1, 6-11, and 27-49 is respectfully requested.

Claims 1, 9, 10, and 13 were rejected under 35 USC §102(b) over Franchini et al. (Vitamin E as Adjuvant in Emulsified Vaccine for Chicks, *Poultry Science*, 1991, 70: 1709-1715, "Franchini"). Applicants respectfully traverse the rejection of these claims over Franchini. Franchini describes the effect of vitamin E as an adjuvant. However, the claimed invention uses an adjuvant component that comprises phytol, isophytol, or a phytol derivative. These components are not vitamin E. Rather, as disclosed in the application, these components are derived from vitamin E. There is no discussion, and the Examiner has not provided any suggestion or proof, that vitamin E *in vivo* metabolizes into one of the adjuvant components prescribed in the present application. Furthermore, the mere fact that vitamin E could be transformed *in vivo* to a phytol, isophytol, or a phytol derivative does not in and of itself anticipate the claimed invention which comprises a composition that has been prepared or a vaccine preparation in unit dosage form that includes the antigen and the adjuvant component. A claim is anticipated only if each and every element as set forth in the claim is found either expressly or inherently in the prior art reference. There is no suggestion or disclosure in the cited

literature that vitamin E, once injected or administered to a patient, would provide a composition in unit dosage form as presently claimed. Therefore, withdrawal of the rejections of claims 1, 9, 10, and 13 over Franchini is respectfully requested.

Claims 1 and 4 were rejected under §102(b) by Lenk et al. (US 5,030,453, "Lenk"). The Applicant respectfully traverses this rejection. Lenk generally describes SPLVs (stable plurilamellar vesicles) (Lenk, col. 5, line 49) as lipid vesicles characterized by supramolecular organization which differs from that of conventional liposomes (*Id.*, col. 8, line 60 and col. 9, line 12, emphasis added). Lenk then generically lists possible SPLV constituents including phytanols. (Id, col. 11, lines 30-63.) Lenk further characterizes the SPLVS as follows: "The SPLVs possess many and occasionally over one hundred bilayers and as such are clearly distinct in the properties from liposomes with a single or few lamellae (e.g. SUVs and LUVs or REVs)." (Id, col. 12, lines 43-45.) At the very least this clearly describes the SPLVs as complex vesicles not a homogeneous solution.

The presently claimed invention recites that the antigen is homogeneously dispersed with the adjuvant component. This is markedly different than the supermolecular organization of the SPLVs described in Lenk. It is believed that Lenk does not describe of make obvious a composition as claimed or even an adjuvant component as recited in the presently-claimed invention. Therefore, withdrawal of this rejection is respectfully requested.

Claim 1 was rejected under §102(e) over Danilov et al. (US 6,525,035, "Danilov"). Danilov describes a composition that includes 1) polyprenol monophosphates of the formula

$$H—[—CH_2\text{-}C(CH_3)=CH—CH_2]_n\text{-}O—P(=O)(OH)_2$$

wherein 2 is an integer from 6-19 inclusive or a salt thereof, and 2) a polyprenol pyrophosphate of the formula:

$$H—\ [—CH_2\text{-}C(CH_3)=CH—CH_2)_m—O—P(=O)(OH)\ —O—P(=O)(OH)_2$$

wherein m is an integer from 6-19 inclusive or a salt thereof. (Danilov, col. 1, line 60 through col. 2, line 6.) Each of these polyprenols are polyunsaturated species. The polyprenol compound disclosed and described in Danilov is a different species than that presently recited in claim 1. Claim 1 recites an adjuvant component that includes phytol, isophytol, and phytol derivative. The species recited in claim 1 are not polyunsaturated. Therefore, it is believed that Danilov does not disclose or make obvious the claimed invention. Therefore, withdrawal of the rejection over Danilov is requested.

Conclusion

Applicants respectfully request timely examination of this application leading to allowance of all elected claims. The Examiner is invited to contact the undersigned attorney by telephone if there are any questions about this Response or other issues that may be resolved in that fashion.

Respectfully submitted,

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